IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KING DRUG COMPANY OF FLORENCE, INC., et al., Plaintiffs, v. CEPHALON, INC., et al., Defendants.	:	CIVIL ACTION No. 2:06-cv-1797
VISTA HEALTHPLAN, INC., et al., Plaintiffs, v. CEPHALON, INC., et al., Defendants.	:	CIVIL ACTION No. 2:06-cv-1833
APOTEX, INC., Plaintiff, v. CEPHALON, INC., et al., Defendants.	:	CIVIL ACTION No. 2:06-cv-2768

Goldberg, J. **November 5, 2015**

MEMORANDUM OPINION

Presently before me are numerous motions to preclude expert testimony pursuant to Federal Rule of Evidence 702 and Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). These motions are filed in the consolidated antitrust lawsuits referred to as the In re Modafinil Litigation, which focuses on four "reverse-payment" settlement agreements entered

into by a pharmaceutical company and several generic drug manufacturers.[1] Plaintiffs, Direct Purchasers and End Payors of Provigil, and a generic competitor, Apotex, Inc., seek to preclude Defendants from offering the opinions of several experts regarding the validity and enforceability of U.S. Patent No. RE 37,516 ("the RE '516 patent"), as well as testimony on whether the Generic Defendants' modafinil products infringed this patent.[2] Resolving these motions requires the application of previous rulings I have made in the related patent litigation, Apotex, Inc. v. Cephalon, Inc., as well as the interpretation of the United States Supreme Court's recent pronouncement on reverse-payment settlement agreements in Federal Trade Commission v. Actavis, Inc., 133 S. Ct. 2223 (2013).

For the reasons that follow, Plaintiffs' motions will be granted in part and denied in part.

[1] These agreements were entered into by Defendant, Cephalon, Inc. ("Cephalon"), the brand-name manufacturer of Provigil, and the following Defendant generic drug manufacturers: Barr Pharmaceuticals, Inc. ("Barr"); Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (collectively "Mylan"); Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (collectively "Teva"); and Ranbaxy Laboratories, Ltd. and Ranbaxy Pharmaceuticals, Inc. (collectively "Ranbaxy") (collectively referred to as the "Generic Defendants").

[2] The Federal Trade Commission ("FTC") was also a plaintiff in this action, but recently settled its dispute with Cephalon. Nonetheless, one of the motions addressed in this opinion is the FTC's "Motion to Exclude Opinions of Cephalon's Ten Patent Experts." Due to prior collateral estoppel rulings described infra, this motion was granted as to the FTC only. However, because the Private Plaintiffs joined the FTC's motion to preclude these experts, I will also address the FTC's motion herein. (See Dkt. No. 06-1797, Doc. No. 615; Dkt. No. 06-1833, Doc. No. 297; Dkt. No. 06-2768, Doc. No. 697.)

Some of the Private Plaintiffs have also settled with certain Defendants. However, all Private Plaintiffs have claims remaining, and all of the motions addressed in this Opinion have been joined by other Plaintiffs (e.g. Plaintiffs who did not originally file the specific motions at issue). Therefore, all of these motions remain relevant despite various settlements.

I. FACTUAL AND PROCEDURAL BACKGROUND

A. Factual History

In 1997, Cephalon was issued U.S. Patent No. 5,618,845, covering specific formulations of modafinil, the active pharmaceutical ingredient ("API") in Provigil. Cephalon was granted a reissue patent on modafinil, the RE '516 patent, in 2002. Modafinil is a wakefulness-promoting agent used to treat narcolepsy and other sleep disorders. On December 24, 2002, the Generic Defendants each filed an Abbreviated New Drug Application ("ANDA") seeking to market a generic version of Provigil, and each filed a Paragraph IV certification with the FDA indicating that Cephalon's RE '516 patent was either invalid or the generic products did not infringe the patent. In 2003, Cephalon filed suit against the Generic Defendants for patent infringement ("the Paragraph IV litigation").

The Paragraph IV litigation between Cephalon and the Generic Defendants settled between December 2005 and February 2006, with the Generic Defendants agreeing to forego releasing their generic modafinil products until April 6, 2012. Plaintiffs in the antitrust case allege that in return for the Generic Defendants agreeing to settle the Paragraph IV litigation and stay off of the market until 2012, Cephalon paid the Generic Defendants millions of dollars, in violation of antitrust laws.[3] This type of settlement—referred to as a reverse-payment settlement—was recently analyzed by the United States Supreme Court in Actavis.

In addition to the Actavis claims, Plaintiffs have also brought antitrust claims for Walker Process fraud against Cephalon, alleging that Cephalon obtained the RE '516 patent "by knowingly and willfully misrepresenting facts to the Patent Office." See Walker Process Equip.,

[3] Greater detail about these settlements can be found in this Court's January 28, 2015 Opinion addressing Defendants' motions for summary judgment. See King Drug Co. of Florence, Inc. v. Cephalon, Inc., 88 F. Supp. 3d 402 (E.D. Pa. 2015).

Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177 (1965). Apotex has also alleged that the Paragraph IV litigation constituted sham litigation, in violation of the Sherman Act.

B. Procedural History

1. The Apotex Patent Litigation

In addition to the above-mentioned antitrust claims, Apotex also brought claims against Cephalon seeking a declaratory judgment that the RE '516 patent was invalid, unenforceable and not infringed by Apotex's generic Provigil product. After holding two bench trials, I made a number of rulings on Apotex's claims for a declaratory judgment regarding the RE '516 patent.

Following the first bench trial, I held that the RE '516 patent was invalid for several reasons: (1) an on-sale bar because "[t]he invention claimed was on sale more than one year prior to the date of the application for the patent"; (2) derivation because "[t]he claimed invention was actually invented by a French company, Laboratoire L. Lafon"; and (3) obviousness, as "[t]he subject matter at issue as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." Apotex, Inc. v. Cephalon, Inc., 2011 WL 6090696, at *1, 13-24 (E.D. Pa. Nov. 7, 2011), aff'd, 500 Fed. Appx. 959 (Fed. Cir. 2013) (per curiam).

In the same bench trial, I also determined that the RE '516 patent was unenforceable due to Cephalon's inequitable conduct in the procurement of the patent. In reaching this conclusion, I found that Cephalon had misrepresented and omitted material information in applying for the RE '516 patent with the specific intent to deceive the United States Patent and Trademark Office ("PTO"). Id. at *25-28. This holding largely hinged on Cephalon's "concealment of another company's extensive involvement in the product which [was] the subject of the claimed invention" and "affirmatively t[elling] the PTO that it had modified particle size when in fact it

had done nothing whatsoever to change, modify or improve the modafinil it received from Lafon." Id. at *27.

I addressed the issue of infringement in the second bench trial. This dispute largely concerned the size of the modafinil particles that make up the pharmaceutical composition described in the RE '516 patent as compared to Apotex's generic Provigil ANDA. Following a Markman hearing, I determined that Cephalon's RE '516 patent claimed "a pharmaceutical composition of modafinil wherein at least 95% of the modafinil particles have a diameter of less than 220 microns (μm)." In comparison, Apotex's ANDA required that "only 25-80% of the modafinil particles have a diameter of less than 220μm." Apotex, Inc. v. Cephalon, Inc., 2012 WL 1080148, at *1 (E.D. Pa. Mar. 28, 2012).

During the second bench trial, Cephalon offered the testimony of a number of infringement experts. Relevant to the Daubert motions presently before me was the testimony of Dr. David Bugay, who performed a number of tests on the size of the modafinil particles in Apotex's Canadian modafinil product in an effort to demonstrate that Apotex's product infringed the RE '516 patent. I rejected Dr. Bugay's testimony, finding that "while [I] need not rest [my] conclusion upon a finding that Dr. Bugay's testing is flawed, the variation [in his results] nonetheless renders Cephalon's testing an unreliable basis for the conclusion that 95% of the modafinil particles in any of Apotex's Canadian tablets are smaller than 220μm." Id. at *12. Ultimately, I concluded that "Cephalon ha[d] not produced sufficient evidence to demonstrate that the milling step reduce[d] particle size to such a degree that the pharmaceutical composition produced pursuant to Apotex's ANDA" infringed the RE '516 patent. Id. at *16.

2. The Collateral Estoppel Opinions

After the conclusion of the patent trials, and following the Supreme Court's Actavis decision, I considered whether my findings that the RE '516 patent was invalid and procured by fraud would have any preclusive effect in the Private Plaintiffs' antitrust cases. This analysis largely focused on Cephalon's Seventh Amendment right to a jury trial and whether Cephalon had waived that right by failing to object on Seventh Amendment grounds when Apotex moved to bifurcate its patent and antitrust claims. King Drug Co. of Florence, Inc. v. Cephalon, Inc., 2014 WL 982848, at *7 (E.D. Pa. Mar. 13, 2014).

My decision regarding the preclusive effect of the intent to defraud element of inequitable conduct was complicated by the fact that after the patent trial evidence had closed, but before I issued my findings, the United States Court of Appeals for the Federal Circuit heightened the standard of proof for inequitable conduct to require clear and convincing evidence that the patentee acted with the specific intent to deceive the PTO. See Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276 (Fed. Cir. 2011). Prior to Therasense, the intent to defraud element could be satisfied by evidence of gross negligence—which is insufficient to establish fraudulent intent in a Walker Process claim. King Drug Co. of Florence, Inc., 2014 WL 982848, at *3-5. Given the timing of these decisions, I found that Cephalon could not have known that any findings of intent to defraud in the inequitable conduct context could have a preclusive effect on Plaintiffs' Walker Process claims. Accordingly, I determined that Cephalon had not waived its Seventh Amendment right as to the intent prong of Walker Process, and that Cephalon could raise the issue of fraudulent intent (or lack thereof) before the antitrust jury. Id. at *10-11.

Regarding invalidity of the RE '516 patent and the materiality element of Plaintiffs' Walker Process claims, I concluded that, by failing to object on Seventh Amendment grounds at the time of bifurcation, Cephalon had waived its right to contest these issues at the antitrust trial, and therefore, collateral estoppel applied. Id. at *12. As to the Generic Defendants, I found that "[t]he fact that the patent was found invalid in the 2011 Apotex patent litigation should have no bearing on the proofs necessary to hold the Generic Defendants liable for antitrust violations . . . [and] [t]he Generic Defendants will still be able to argue, should they so choose, that settlement was pro-competitive, and that they were unaware of Cephalon's alleged fraud or the invalidity of the patent." Id. at *13.

With trial pending, it may be useful to restate here which issues have been decided and may not be revisited: (1) the RE '516 patent is invalid due to the on-sale bar, derivation and obviousness; and (2) the materiality prong of Walker Process fraud has been established. Consequently, and as will be explained in greater detail infra, any expert opinions contrary to these holdings will not be permitted.

It is also my intention to explain to the jury that these issues have been previously decided, must be accepted, and are not for their consideration. This explanation will come by way of instructions prior to opening statements and the taking of testimony. I will, of course, accept input from counsel as to how these concepts should be conveyed to the jury, but care will be taken to ensure that Defendants' rights in defending the antitrust allegations will be protected.

3. The Actavis Standard

Most recently, I provided direction on the burdens of proof and structure of the rule of reason analysis under Actavis. I held that Plaintiffs' Actavis claims would follow a rule of reason, burden-shifting analysis, with Plaintiffs bearing the initial burden of demonstrating

anticompetitive effects, including evidence of a large reverse payment. The burden then shifts to Defendants to demonstrate procompetitive effects, including justifications for the reverse payments, such as fair value for services and avoided litigation costs. Plaintiffs then have an opportunity to rebut those justifications and demonstrate to the jury that the reverse payments were not reasonably necessary to achieve the alleged procompetitive benefits, and instead, were aimed at delaying generic entry. After considering all of the above, the jury determines whether Defendants' conduct was, on balance, unreasonably anticompetitive. See King Drug Co. of Florence, Inc. v. Cephalon, Inc., 2015 WL 356913, at *10-11, 14, 17 (E.D. Pa. Jan. 28, 2015).

4. The Pending Motions to Preclude Defendants' Patent Experts

Cephalon has identified ten patent experts who may testify at the antitrust trial. Their opinions can be divided into several subcategories, and different challenges have been raised regarding each subcategory. For example, Dr. Eugene Cooper, Mr. Bruce Stoner and Dr. Joseph Baranski all present opinions on issues relating to the validity of the RE '516 patent. Dr. Markus Antonietti, Dr. David Bugay, Dr. Lynn Van Campen and Dr. Robert Williams all offer opinions on issues relating to whether the Generic Defendants' modafinil products infringe Cephalon's RE '516 patent. Finally, Dr. Gerald Dahling, Mr. Paul Gardner,[4] and Mr. Peter Ludwig[5] present opinions on the reasonableness of the validity, enforceability and infringement arguments raised by Defendants during the Paragraph IV litigation and Defendants' decisions to settle.

Plaintiffs have raised numerous challenges to these experts under Daubert. The Direct Purchasers and End Payors argue that all of Cephalon's patent experts' opinions should be

[4] Mr. Gardner has been retained by the Mylan Defendants, but all other Defendants have also designated him as an expert witness.

[5] Mr. Ludwig has been retained by Ranbaxy, but all other Defendants have also designated him as an expert witness.

excluded because they do not fit any issue the jury will consider under the standards set forth in Actavis. Additionally, all Plaintiffs challenge the validity and infringement experts for reliability and fit, and point out numerous inconsistencies between the experts' opinions and prior rulings by this Court in the Apotex patent litigation. All Plaintiffs also raise questions about the qualifications of certain experts to opine about Cephalon's subjective intent for purposes of the Walker Process claims. Finally, Apotex challenges the "reasonableness" experts for presenting impermissible legal opinions that usurp the roles of the judge and jury.

Defendants respond that the testimony in question will not be offered to prove that the RE '516 patent is valid, or, as to Cephalon, that any misrepresentations made to the PTO were not material—issues that Defendants acknowledge they are estopped from litigating. Instead, Defendants respond that these experts will assist the jury in determining whether the settlements were reasonable and procompetitive under Actavis. Defendants further explain that this testimony will demonstrate that the settlements were motivated, at least in part, by litigation uncertainty, as opposed to having any anticompetitive aim. Finally, Cephalon offers these opinions to demonstrate that it had a reasonable basis to bring the infringement claims against the Generic Defendants in response to Apotex's sham litigation claim.

II. LEGAL STANDARD

While Federal Rule of Evidence 702 and precedent interpreting that rule (in particular, Daubert) have many components, the issues presently before me mostly pertain to the question of whether the proffered opinions "fit" with the relevant issues in the case. Nonetheless, a brief review of Rule 702 and Daubert is useful.

Rule 702 governs the admissibility of expert testimony, and states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Rule 702 "embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit." Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003) (quoting In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741-43 (3d Cir. 1997)). In evaluating whether an expert opinion is admissible, the district court acts as a gatekeeper, excluding opinion testimony that does not meet these requirements. Id. The burden is on the party offering the evidence to establish admissibility by a preponderance of the evidence. Padillas v. Stork-Gamco, Inc., 186 F.3d 412, 418 (3d Cir. 1999).

An expert is qualified if he or she has specialized knowledge "greater than the average layman." Waldorf v. Shuta, 142 F.3d 601, 625 (3d Cir. 1998) (quoting Aloe Coal Co. v. Clark Equip. Co., 816 F.2d 110, 114 (3d Cir. 1987)). This requirement is interpreted liberally, as "a broad range of knowledge, skills, and training qualify an expert." Schneider, 320 F.3d at 404.

Reliability requires that an expert's opinion is based upon "'methods and procedures of science' rather than on 'subjective belief or unsupported speculation.'" In re Paoli, 35 F.3d at 742 (quoting Daubert, 509 U.S. at 590). In considering whether an expert's method is reliable, courts should consider: (1) whether it is based upon testable hypotheses; (2) whether the method has been subject to peer review; (3) the known or potential error rate; (4) "the existence and maintenance of standards controlling the technique's operation"; (5) whether it is generally accepted; (6) the relationship of the technique to other methods that have been deemed reliable; (7) the expert's experience or qualification with the technique or method; (8) non-judicial uses the method has been put to; and (9) all other relevant factors. Id. at 742 n.8.

The reliability requirement is not to be applied "too strictly" and is satisfied as long as the expert has "good grounds" for his or her opinion. Holbrook v. Lykes Bros. S.S. Co., Inc., 80 F.3d 777, 784 (3d Cir. 1996). "Proponents of expert testimony do not have to 'prove their case twice—they do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of the evidence that their opinions are reliable.'" In re DVI, Inc. Sec. Litig., 2014 WL 4634301, at *5 (E.D. Pa. Sept. 15, 2014) (quoting In re Paoli, 35 F.3d at 744) (emphasis in original).

There also must be a "valid scientific connection" or "fit," between the facts of the case and the expert's opinion. Daubert, 509 U.S. at 591-92; see also Holbrook, 80 F.3d at 777. This requirement ensures that the opinion is relevant and will "assist the trier of fact to understand the evidence or to determine a fact in issue." Daubert, 509 U.S. at 591. Finally, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Id. at 596 (citing Rock v. Arkansas, 483 U.S. 44, 61 (1987)).

III. LEGAL ANALYSIS

A. The Relevance of Opinions Offered to Demonstrate the Strength of Defendants' Patent Positions

Before delving into the specific challenges raised against individual experts, I will first address Plaintiffs' blanket challenge to any defense expert testimony offered to establish the strength of Defendants' patent positions in the Paragraph IV litigation. Plaintiffs argue that this evidence is irrelevant under Actavis.[6]

[6] Plaintiffs do not, however, dispute that this evidence would be relevant to rebut Apotex's sham litigation claim. See Professional Real Estate Investors v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60 (1993) (In sham litigation case, "[i]f an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under [E. R.R.

Throughout the course of this litigation, Plaintiffs have continually indicated that they intend to introduce evidence regarding the weakness of the RE '516 patent in the antitrust trial. Plaintiffs have asserted that this evidence is relevant to establish Defendants' knowledge that the RE '516 patent was invalid, procured by fraud, and not infringed, and thus, to help establish that Defendants had anticompetitive motivations in entering into the settlement agreements. However, at the same time, Plaintiffs seek to preclude Defendants from responding to this evidence.

Plaintiffs' position is inconsistent. On one hand, Plaintiffs urge that evidence that Defendants knew of the RE '516 patent's weakness is relevant to an Actavis rule of reason analysis while, on the other hand, they insist that evidence regarding the strength of that same patent is irrelevant. The specific parameters of the admissibility, in Defendants' case, of the strength of the patent evidence may depend upon what evidence Plaintiffs are successful in introducing regarding the weakness of the patent. And it may be that even if Plaintiffs decide not to introduce this type of evidence, Defendants may nonetheless seek to include strength of the patent evidence in their case. Without a trial record before me, I am reluctant to draw too many bright lines, and certain evidentiary rulings must be made at trial. But for now, and as it relates to the motions before me, I conclude that if Plaintiffs pursue a theory that a weak patent is probative of antitrust motivations in settling the Paragraph IV litigation, I will allow Defendants to respond and attempt to rebut this evidence.

Indeed, Actavis seems to anticipate the presentation of this type of evidence. See Actavis, 133 S. Ct. at 2231 (explaining that the scope of the patent does not end the antitrust

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Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961)]); Actavis, 133 S. Ct. at 2236 (it may be necessary to litigate patent validity "to determine whether the patent litigation is a sham").

inquiry, but additional relevant considerations include "offsetting legal considerations present in the circumstances, such as here those related to patents"). I recognize that Actavis states that "it is normally not necessary to litigate patent validity to answer the antitrust question" and "the size of [an] unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." Id. at 2236-37. These statements do not mandate, however, that all evidence regarding a patent is inadmissible in a reverse-payment settlement antitrust trial. This is particularly so in the case before me, where Defendants maintain that the purpose of the proffered expert testimony is not to prove the validity of the patent, but instead to demonstrate that a reasonable litigant could have believed the patent to be valid at the time of the reverse-payment settlements.[7]

Defendants' beliefs during the Paragraph IV litigation regarding the strength or weakness of the RE '516 patent speaks directly to the issue of why the settlement agreements were executed. The Supreme Court has stressed that, "[a]lthough the parties may have reasons to prefer settlements that include reverse payments, the relevant antitrust inquiry is: What are those reasons?" Id. at 2237. Evidence that goes to the strength or weakness of Cephalon's patent

[7] I note that this principle does have limitations. Indeed, I recently decided a Daubert motion in this matter regarding the testimony of Defendants' economic experts Bell, Hausman and Snyder, and precluded Cephalon from presenting evidence regarding its own litigation uncertainty—that is, Cephalon could not attempt to justify the reverse-payment settlement agreements with evidence that it sought to avoid the risk of invalidation of the RE '516 patent. King Drug Co. of Florence, Inc. v. Cephalon, Inc., 2015 WL 5783603, at *8 (E.D. Pa. Oct. 5, 2015). In response to the instant motion, Cephalon argued that issues relating to the RE '516 patent were also relevant to establish that the settlements resolved "risks and reduce[d] uncertainty" regarding the "potential loss of its patent." (Ceph.'s Resp., p. 1.) In accordance with my prior ruling, I disagree with Cephalon's position that the risk of losing its patent constitutes a procompetitive justification for the reverse payment. King Drug Co. of Florence, Inc., 2015 WL 5783603, at *8. To be clear, evidence regarding the risk of invalidation is distinguishable from evidence demonstrating that the patent was strong and that the parties could have reasonably believed that the RE '516 patent would have survived the Paragraph IV litigation. Id. at *8-9.

positions may assist the jury in answering this question, as it can provide circumstantial evidence of the settling parties' intentions.

To summarize, while I am not prepared to make specific rulings at this time on evidence that has yet to be presented, I am prepared to state that if Plaintiffs attempt to offer otherwise admissible evidence regarding the weakness of the RE '516 patent, that evidence will be admissible under the rule of reason analysis as evidence that the payments were made to keep the Generic Defendants off of the market. But Plaintiffs must understand that if such evidence is offered and admitted, I will provide Defendants, within the constraints articulated above regarding collateral estoppel, latitude to rebut that evidence. The more complicated question then becomes: What specific form will this evidence take? A careful examination of the proposed testimony of these experts is necessary to answer this question.[8]

B. The Motion to Preclude the Validity Experts – Mr. Stoner and Drs. Cooper and Baranski

1. The Expert Report of Mr. Bruce Stoner

Mr. Bruce Stoner, a patent attorney, testified regarding the RE '516 patent's validity during the Apotex patent trial. His expert report prepared for use in the antitrust case largely incorporates his prior report from the Apotex patent litigation. Mr. Stoner explains the patent prosecution process and the various legal standards applicable to challenges to patent validity at the time of the settlements between Cephalon and the Generic Defendants. (Stoner Exp. Rep., June 10, 2011, ¶¶ 1, 3, 10-22.)

[8] Defendants were ordered to submit an offer of proof as to each of the patent expert witnesses addressed in this opinion. These offers of proof listed, in a summary fashion, the opinions that these experts intend to present at trial, and are largely consistent with the expert reports prepared by these experts.

Mr. Stoner also offers opinions regarding inequitable conduct, and opines that the record evidence he has reviewed would fail to support a finding that Cephalon engaged in inequitable conduct when obtaining the RE '516 patent. (Id. at ¶ 25.) With respect to derivation, Mr. Stoner criticizes Plaintiffs' expert, John J. Doll, and opines that the inventors of the RE '516 patent "did not hide their role (or Lafon's role) or pretend that they had manufactured the modafinil they tested or that they had discovered a new method of preparing modafinil." (Id. at ¶ 36.) Mr. Stoner's opinions on the on-sale bar can be summarized as follows: "I remain of the opinion that there is no evidence that the transfer of modafinil from Lafon to Cephalon under the terms of the Supply and License Agreements creates an on-sale bar under 35 U.S.C. § 102(b)." (Id. at ¶¶ 51, 65.) Finally, Mr. Stoner also disagrees with Doll's opinions on obviousness, relying on his prior expert report in the Apotex matter, and opining that any information withheld from the PTO was not material. (Id. at ¶¶ 54-55.) Mr. Stoner concludes his report with the following: "For the foregoing reasons, it is my opinion that the evidence of record fails to overcome the presumption that the '516 patent and the '845 patent were and are valid and enforceable." (Id. at ¶ 68.)

2. The Expert Report of Dr. Eugene Cooper

Dr. Eugene Cooper, an expert in the field of pharmaceutical formulation and dosage forms, offered his report "in support of the validity of Cephalon's U.S. Patent No. RE37,516." (Cooper Exp. Rep., June 9, 2011, ¶ 1.) He also prepared a report in connection with the Apotex patent trial, as well as the Paragraph IV litigation, and has incorporated his prior expert reports. (Id. at ¶¶ 2, 3.) Dr. Cooper opined that "it is [his] opinion that the '516 patent is valid." (Id. at ¶ 7.)

Dr. Cooper also addresses the on-sale bar, and opines that the invention of the RE '516 patent was not ready for patenting more than one year before the patent application was filed,

and therefore, the on-sale bar did not render the patent invalid. (Id. at ¶ 24.) Additionally with respect to the on-sale bar, he opines that the experimental use and sale doctrine would apply, which would also insulate the RE '516 patent from invalidation. (Id. at ¶¶ 25, 27.) With respect to derivation, Dr. Cooper states that "Cephalon did not derive the claimed invention from Lafon" and "the Cephalon inventors, and not anyone at Lafon" conceived of the invention. (Id. at ¶¶ 28-29.) Finally, Dr. Cooper addresses the issue of obviousness, concluding that, in his opinion, "the claims of the '516 patent would not have been obvious to a person having ordinary skill in the art at the time the invention was made." (Id. at ¶ 38.)

3. The Expert Report of Dr. Joseph Baranski

Dr. Joseph Baranski, an expert on the physical and psychological effect of modafinil on humans and the interpretation of results of modafinil testing, also testified in the Apotex patent matter and prepared a report in connection with the Paragraph IV litigation between Cephalon and the Generic Defendants. He too incorporates the reports he prepared in connection with those actions. (Baranski Exp. Rep., June 8, 2011, ¶ 2.) Dr. Baranski opines that the RE '516 patent is not invalid due to the on-sale bar, and explains that certain trials Cephalon performed on the modafinil it received from Lafon constituted experimental use, which provides an exception to the application of the on-sale bar. (Id. at ¶¶ 9-13.)

4. Analysis

Plaintiffs vigorously challenge the validity experts' testimony that the RE '516 patent is valid and that the omissions to the PTO were not material. Plaintiffs also contest several of the legal standards applied to the validity analyses performed by these experts. Plaintiffs' primary complaint is that this testimony conflicts with my prior rulings, much of which has been given preclusive effect through my collateral estoppel opinion. See King Drug Co. of Florence, Inc.,

2014 WL 982848, at *1 ("collateral estoppel will . . . apply to the invalidity portion of the Apotex patent litigation opinion and precludes Cephalon from relitigating Walker Process materiality"). Plaintiffs urge that because I have already rejected these opinions in the Apotex patent litigation, such opinions must be excluded under Daubert as unreliable and for failure to fit the facts of the case.

Cephalon responds that the mere fact that the Court, sitting as a fact finder in the Apotex patent trial, happened to credit the testimony of an opposing expert or disagreed with the validity experts' conclusions does not mean that these experts' opinions are unreliable under Daubert. Cephalon further argues that this expert testimony is now offered for a different purpose. During the Apotex patent trial, the testimony was offered to show that the patent was, in fact, valid, whereas Cephalon now argues the validity experts' testimony is offered to show that, ex ante, a company in Cephalon's position could have reasonably believed that the RE '516 patent was strong and expected to prevail in the Paragraph IV litigation.

Initially, I agree with Cephalon that the sheer fact that I disagreed with opinions presented by Cephalon's validity experts during the Apotex patent trial does not automatically render their opinions unreliable. See Daubert, 509 U.S. at 595 (reliability inquiry focuses "solely on principles and methodology, not on the conclusions they generate"); FTC v. Cephalon, Inc., 36 F. Supp. 3d 527, 533 (E.D. Pa. 2014) ("The fact that a patent's strength is a spectrum does not change simply because a judge later determines that the patent was, in fact, invalid all along"). Put another way, an expert's opinions are not inadmissible as unreliable solely because I previously found other expert testimony more persuasive.

That said, I nonetheless conclude that the validity expert's opinions that the RE '516 patent is currently valid, and that the on-sale bar, derivation and obviousness do not render the

patent invalid, do not fit the facts of this case and are not admissible. These opinions directly contradict my rulings in the Apotex patent trial, which were upheld on appeal, and which have been given preclusive effect in the antitrust litigation. Such testimony would likely be confusing to the jury and would not assist them in deciding the facts at issue in the antitrust trial, as the validity of the patent has been decided and is no longer in contention. See In re Elec. Books Antitrust Litig., 2014 WL 1282298, at *14-15 (S.D.N.Y. Mar. 28, 2014) (excluding expert testimony of procompetitive effects where prior bench trial found, as a matter of law, the absence of any procompetitive effects).

Cephalon insists that it is not offering these opinions to demonstrate that the RE '516 patent is valid. Instead, Cephalon explains that the purpose of these opinions is to convince the jury that it would have been reasonable for Cephalon to believe in the RE '516 patent's merits at the time of the reverse-payment settlements. As previously discussed, I find that an ex ante exploration of the validity opinions presented in connection with the Paragraph IV litigation can be offered by Defendants.[9] However, these experts may not opine that they still believe the patent to be valid, or that they do not believe materiality has been established, as those opinions do not fit the facts of the case and are not helpful to the jury.

Cephalon also indicates that some of these experts' opinions will "help the jury understand the validity . . . questions in the patent litigation." (Ceph. Resp., p. 2.) Mr. Stoner's report does provide a recitation of the patent prosecution process and the legal standards

[9] As will be explored infra, an expert will not be permitted to testify at trial that certain legal arguments made during the Paragraph IV litigation were "reasonable" or that Cephalon could have reasonably had a realistic expectation of success on the merits. However, that does not mean that Cephalon cannot offer evidence aimed at convincing the jury that their positions were reasonable, such as explanation of the arguments made and opinions presented during the Paragraph IV litigation. So long as these experts do not directly opine upon reasonableness, I do not have the same concern that the experts are presenting an impermissible legal opinion.

applicable to challenges to patent validity at the time of the reverse-payment settlements. (Stoner Exp. Rep., June 10, 2011, ¶¶ 1, 3, 10-22.) Many of Mr. Stoner's opinions on the basic legal standards and the patent prosecution process have not been challenged by Plaintiffs on the grounds that they are inaccurate or unreliable, and therefore, as long as such opinions are consistent with applicable precedent, they may be presented to the jury. United States v. Univ. Rehab Servs., Inc., 1996 WL 297575, at *10 (E.D. Pa. May 31, 1996) ("expert testimony is viewed as helpful in cases, like this one, involving complex statutes or issues outside the general knowledge of the jury").

Plaintiffs do, however, challenge certain legal standards presented by these experts as unreliable and inconsistent with my prior rulings. For example, with respect to derivation, Plaintiffs challenge Mr. Stoner's opinion that Lafon needed to appreciate the significance of the smaller particle size described in the RE '516 patent in order to meet the conception prong of derivation. (Stoner Exp. Rep., Nov. 12, 2010, ¶ 79.) I disagreed with this position in my Opinion declaring the RE '516 patent invalid. See Apotex, Inc., 2011 WL 6090696, at *20 ("whether Lafon had this appreciation is immaterial"). I agree with Plaintiffs and hold that the validity experts will not be permitted to testify as to any legal standard that was explicitly rejected by this Court during the Apotex litigation. See Herbert v. Lisle Corp., 99 F.3d 1109, 1117 (Fed. Cir. 1996) ("Incorrect statements of law are no more admissible through 'experts' than are falsifiable scientific theories").

Finally, Plaintiffs challenge Mr. Stoner's opinions regarding Cephalon's intent to deceive the PTO, arguing that he is not qualified to present opinions on a party's intent or state of mind. I have previously ruled in a separate opinion that an expert may not opine as to the subjective intent or state of mind of another. King Drug Co. of Florence, Inc., 2015 WL 5783603, at *6

(citing In re Rosuvastatin Calcium Patent Litig., 2009 WL 4800702, at *8 (D. Del. Dec. 11, 2009) ("Generally, expert witnesses are not permitted to testify regarding 'intent, motive, or state of mind, or evidence by which such state of mind may be inferred.'"); In re Rezulin Prods. Liab. Litig., 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004) ("Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony")). Accordingly, Mr. Stoner may not opine upon whether Cephalon had intent to defraud the PTO.

C. The Motion to Preclude the Opinions on Infringement – Drs. Antonietti, Bugay, Van Campen and Williams

1. The Expert Report of Dr. Markus Antonietti

Dr. Markus Antonietti, an infringement expert, provides opinions as to whether the Generic Defendants' generic Provigil would have infringed Cephalon's RE '516 patent. He prepared expert reports on behalf of Cephalon in the Apotex litigation and the Paragraph IV litigation, all of which he incorporates into his most recent report. (Antonietti Exp. Rep., June 10, 2011, ¶¶ 2-4.) Dr. Antonietti provides his interpretations of Claims 7 and 13 in his report, which differ from the claim construction performed by this Court in the Apotex litigation. He presents his own interpretation of these claims, opining that the term "at least about 95% of the cumulative total of said particles" in Claim 7 would be understood by one of ordinary skill in the art to refer to the modafinil particles that are in the effective amount only. He also opines that the RE '516 patent requires measurement of particle size distribution using a Hiac/Royco instrument. I rejected both of these opinions when completing the claim construction of the RE '516 patent. See Apotex, Inc. v. Cephalon, Inc., 2010 WL 3933274, at *1 (E.D. Pa. Oct. 7, 2010). Dr. Antonietti also opines that "the proposed generic versions of Provigil infringe the claims of the '516 patent," relying upon his interpretation of RE '516 patent and the test results generated by Dr. Bugay, which are discussed below. (Id. at ¶¶ 36-52.)

2. The Expert Report of Dr. David Bugay

Dr. David Bugay, a chemist, prepared expert reports in connection with the Paragraph IV litigation between Cephalon and the Generic Defendants, and has incorporated those findings into the report he prepared for the antitrust case. (Bugay Exp. Rep., June 10, 2011, ¶¶ 4-5.) Dr. Bugay performed an analysis of the size of the particles in the Generic Defendants' generic Provigil products using a Hiac/Royco brand light obscuration system.[10] These results were then used by Cephalon and other experts retained by Cephalon to demonstrate that the particle size of the Generic Defendants' products infringed the RE '516 patent. (Id. at ¶ 11; Bugay Exp. Rep., Jan. 13, 2005, ¶¶ 9, 18.) Dr. Bugay also tested various samples that had been prepared by another Cephalon expert, Dr. Lynn Van Campen, using "a tablet disintegration procedure to isolate the modafinil in each of the [Generic] [D]efendants' tablets." (Bugay Supp. Exp. Rep., Jan. 22, 2005, ¶ 9.) In his most recent expert report, Bugay opines that "[t]he results [he] reported in connection with [his] work on the [Paragraph IV litigation] were accurate and obtained in a scientifically appropriate manner at the time [he] reported them, and [he] believe[s] they continue to be so today." (Bugay Exp. Rep., June 10, 2011, ¶ 11.)

As demonstrated by the tables in the Direct Purchasers' briefing, which summarizes the particle size data contained in Dr. Bugay's expert reports,[11] Dr. Bugay's results contain significant disparities. For example, when Dr. Bugay tested Teva's modafinil active pharmaceutical ingredient ("API"), he separated one sample of API into three "preps." He then

[10] "'Light obscuration' measures particle size by passing individual particles of a pharmaceutical substance between a light source and an electronic sensor. The electronic sensor records the magnitude of light that is blocked by each of the particles and, based upon that reading, determines their size." Apotex, Inc., 2012 WL 1080148, at *5.

[11] Cephalon does not dispute that these tables accurately summarize the data from Bugay's expert reports.

tested each prep a total of four times. The results of tests performed on the same prep differed by more than 200 µm, and after thirty-six total tests on three Teva samples, twenty-three of the particle size values fell outside of the scope of the RE '516 patent, while thirteen fell inside of its scope. (DPP Infring. Br., Table A.) This same variation could be found in the testing of all of the Generic Defendants' API, as well as the tests performed on the tablet samples prepared by Dr. Van Campen. (See id., Tables B-G.)

3. The Expert Report of Dr. Lynn Van Campen

Dr. Lynn Van Campen, a pharmaceuticals expert, prepared expert reports in connection with the Paragraph IV litigation, as well as the Apotex litigation, and also testified at the Apotex infringement trial. She incorporates those opinions into her report for the antitrust case. (Van Campen Exp. Rep., June 7, 2011, ¶¶ 2-5.) Dr. Van Campen was involved in the separation and isolation of modafinil particles from the Generic Defendants' generic Provigil tablets for processing by Dr. Bugay, and ultimately, for the infringement analysis performed by Dr. Antonietti. She opines that this process was scientifically valid and did not affect the particle size distribution. (Van Campen Exp. Rep., Jan. 21, 2005, ¶¶ 11, 21.)

4. The Expert Report of Dr. Robert Williams

Dr. Robert O. Williams, III, a pharmaceuticals expert, opines upon whether the Generic Defendants' generic Provigil products infringe the RE '516 patent. He prepared an expert report in connection with the Apotex litigation, and incorporates that report by reference. (Williams Exp. Rep., June 10, 2011, ¶¶ 1-3.) In his opinion, "each of the ANDA modafinil products proposed by [the Generic Defendants] meets the particle size limitations of the '516 patent's claims either literally or under the doctrine of equivalents." (Id. at ¶ 8.) He also asserts that one

of ordinary skill in the art would have reached this same conclusion at the time of the reverse-payment settlements. (Id. at ¶ 9.)

More specifically, Williams opines that "the modafinil in Ranbaxy's and Teva's ANDA modafinil products meets the particle size limitation recited in claim 1 of the '516 patent at least under the doctrine of equivalents." (Id. at ¶ 26.) Ranbaxy and Teva's tablets, according to Williams, perform substantially the same function in substantially the same way to achieve substantially the same result as Cephalon's Provigil. (Id. at ¶ 32.) In conducting his analysis, Williams adopts the claim construction opinions of Dr. Antonietti, which conflict with this Court's claim construction. He also adopts Dr. Antonietti's opinions regarding literal infringement. (Id. at ¶¶ 39, 42.)

Dr. Williams opines that, "[b]ased on Dr. Antonietti's interpretation of the claims of the '516 patent . . . in [his] opinion, all bioequivalent generic Provigil products would infringe all the asserted claims of the '516 patent literally or under the doctrine of equivalents." (Id. at ¶ 42.) This opinion is driven by the fact that the unique feature under the RE '516 patent is the size of the particles, which results in greater potency. Any generic version of Provigil would need to be bioequivalent, which "is defined as equivalence in the rate and extent of absorption of two drug products." (Id. at ¶ 43.) Therefore, Dr. Williams concludes that if a generic product is bioequivalent, it would necessarily infringe under the doctrine of equivalents.

5. Analysis

Plaintiffs argue that the infringement experts' testimony should be excluded for several reasons. First, they assert that all opinions on whether the Generic Defendants' Provigil products infringe the RE '516 patent are irrelevant because an invalid patent cannot be infringed. Cephalon responds that it "will not offer their testimony to establish infringement as a fact."

(Ceph. Resp., p. 11.) Instead, Cephalon seeks to convince the jury that it would be reasonable for a company in Cephalon's position to believe that the Generic Defendants' products infringed its patent when it brought suit and ultimately settled the Paragraph IV litigation. For the reasons detailed above, I find that Actavis' rule of reason analysis does not foreclose evidence that seeks to demonstrate the strength of Defendants' patent positions at the time of the settlements.

However, "[i]t is axiomatic that one cannot infringe an invalid patent." Commil USA, LLC v. Cisco Sys., Inc., 720 F.3d 1361, 1368 (Fed. Cir. 2013). As this Court has already ruled that the RE '516 patent is invalid, and collateral estoppel applies to that ruling, Cephalon's experts will not be permitted to opine that the Generic Defendants' products presently infringe the RE '516 patent. Such testimony would not fit the facts of this case and has the potential to confuse the jury. Therefore, these experts should limit their testimony to exploration of the infringement opinions and arguments raised by the parties at the time of the Paragraph IV litigation on an ex ante basis.

Plaintiffs also specifically object to Dr. Bugay's opinions, arguing that, during the Apotex patent litigation, I found his methodology and conclusions unreliable, and that the same result should apply here. The procedures described above for testing the particle size of the Generic Defendants' API and generic Provigil tablets were also used to test Apotex's generic product during the Apotex litigation. Upon closely reviewing the data produced by Dr. Bugay in the Apotex litigation, I determined that "a great deal of variation exist[ed] between the average 95% cumulative values of the six samples," and further found unexplained variation when the same prep of the same sample was tested more than once. Apotex, Inc., 2012 WL 1080148, at *11. Ultimately, I concluded that "the significant variation in Dr. Bugay's results raises serious concerns about the reliability of the protocol and testing insofar as it relates to the question of

infringement." Id. at *12. I stopped short of stating that Dr. Bugay's testing was flawed, but found that "the variation nonetheless renders Cephalon's testing an unreliable basis for the conclusion that 95% of the modafinil particles in any of Apotex's Canadian tablets are smaller than 220 µm." Id. Furthermore, because Dr. Antonietti relied heavily upon the testing performed by Drs. Van Campen and Bugay, I rejected his conclusion that "the milling step described in Apotex's ANDA would reduce particle size enough to bring the final tablet within the claims of the RE '516 patent." Id. at *16.

Plaintiffs argue that the same testing method that I found to be unreliable in the Apotex litigation has been utilized by Dr. Bugay in the antitrust case, and that his results are similarly plagued by unexplained variability. Accordingly, Plaintiffs assert that Dr. Bugay's opinions should be excluded as unreliable under Daubert. Cephalon responds that while this Court disagreed with Dr. Bugay's opinion in the Apotex litigation, it did not strike his opinion from the record as unreliable. Instead, it argues, the Court disagreed with his opinion in making a credibility determination, and therefore, Plaintiffs' concerns with the variation in Dr. Bugay's results should go to weight, not admissibility.

I agree with Plaintiffs that the variation in Dr. Bugay's testing indicates that his opinions should be excluded as unreliable. My concerns with Dr. Bugay's methodology in the Apotex litigation went beyond mere credibility determinations, as I clearly stated that his opinions were an unreliable basis for determining infringement. Id. at *12. While I denied a Daubert motion challenging Dr. Bugay's opinions prior to the Apotex infringement trial, Apotex did not challenge the variability in Dr. Bugay's results at that time. Furthermore, "[i]n the context of preparing for a bench trial, it is not necessary to apply the Daubert standard with full force in advance of trial . . . [as] the court has the flexibility to allow testimony provisionally and revise

its view once the testimony is taken." Alco Indus., Inc. v. Wachovia Corp., 527 F. Supp. 2d 399, 405 (E.D. Pa. 2007).

The same substantial variations that existed in Dr. Bugay's results in the Apotex litigation also appear throughout his testing of the Generic Defendants' API and tablets. The results show that where the same sample of the same product was tested several times using the same methodology, the particle size measurements would vary considerably, ranging from infringing to noninfringing. Cephalon responds that Plaintiffs have failed to support their motion with expert opinions or other evidence to show that the variability is so severe that it renders the results inadmissible. However, it is Cephalon's burden, as the party offering Dr. Bugay's opinions, to prove its admissibility by a preponderance of the evidence. See Padillas v. Stork-Gamco, Inc., 186 F.3d 412, 418 (3d Cir. 1999) ("the burden of establishing admissibility by a preponderance of the evidence . . . is on the proponent") (citations omitted). Cephalon provides no explanation for the variation in Dr. Bugay's results, despite my previous misgivings in the Apotex litigation. Therefore, Dr. Bugay's conclusions stemming from his testing of the Generic Defendants' generic Provigil API and tablets using the Hiac/Royco brand light obscuration system are excluded as unreliable.[12]

Next, Plaintiffs challenge Drs. Antonietti's and Williams' opinions on claim construction that conflict with this Court's claim construction ruling, arguing that these opinions do not fit the facts of the case. When adopting the claim construction opinions of Dr. Antonietti, Dr. Williams' expert report states:

> I am aware of and have reviewed the Court's claim construction Order dated October 6, 2010 . . . and I respectfully disagree with those constructions that would apply the particle size limitation of claim 7 to all measurable particles in

[12] Infringement opinions put forth by other experts that rely upon Dr. Bugay's testing and results will also be excluded as unreliable.

> the pharmaceutical composition, and with those constructions that permit particle size to be measured by any conventional method.

(Williams Exp. Rep., June 10, 2011, ¶ 39 n.4.) Cephalon clarifies that the opinions on claim construction are offered to show "what Cephalon could reasonably have believed in 2005—before any court had issued an opinion on claim construction." (Ceph.'s Resp., p. 12.) For the reasons set forth above, I find that evidence that helps to explain, on an ex ante basis, what Cephalon could have reasonably believed about the claim construction of the RE '516 patent is permissible and may be explored through these experts.

Finally, Plaintiffs challenge Dr. Williams' opinion that "any bioequivalent generic form of Provigil would fall within the scope of claim 1, at least under the doctrine of equivalents, and literally within the scope of claim 7." (Williams Exp. Rep., June 10, 2011, ¶ 43.) Plaintiffs assert that simply assuming any bioequivalent version of generic Provigil would infringe the RE '516 patent is contrary to law, and therefore, is unreliable under Daubert. Plaintiffs rely upon Abbott Laboratories v. Sandoz, Inc., 566 F.3d 1282 (Fed. Cir. 2009), for support, where the United States Court of Appeals for the Federal Circuit stated as follows:

> While bioequivalency may be relevant to the function prong of the function-way-result test,[13] bioequivalency and equivalent infringement are different inquiries. Bioequivalency is a regulatory and medical concern aimed at establishing that two compounds are effectively the same for pharmaceutical purposes. In contrast, equivalency for purposes of patent infringement requires an element-by-element comparison of the patent claim and the accused product, requiring not only equivalent function but also equivalent way and result. Different attributes of a given product may thus be relevant to bioequivalency but not equivalent infringement, and vice versa. . . . If bioequivalency meant per se infringement, no alternative to a patented medicine could ever be offered to the public during the life of the patent. Thus, while potentially relevant, the bioequivalency of an

[13] "The primary test for equivalency is the 'function-way-result' test or 'triple identity' test, whereby the patentee may show an equivalent when the accused product or process performs substantially the same function, in substantially the same way, to achieve substantially the same result, as disclosed in the claim." Sandoz, Inc., 566 F.3d at 1296.

> accused product with a product produced from the patent at issue is not sufficient to establish infringement by equivalents.

Id. at 1298 (citation and quotation marks omitted). This principle is further buttressed, argue Plaintiffs, by this Court's finding of noninfringement for Apotex's bioequivalent generic Provigil product during the Apotex litigation.

Additionally, Plaintiffs argue that neither Dr. Williams, nor any other Cephalon expert, offered any opinions based on the doctrine of equivalents during the Paragraph IV litigation. Therefore, according to Plaintiffs, Dr. Williams' opinions could not have been the basis for any of Cephalon's beliefs regarding its infringement case at the time of the reverse-payment settlements. Defendants respond that they are not seeking to establish infringement as fact, but instead intend to show that it would have been reasonable for Defendants to believe that Cephalon would prevail on its infringement claims at the time of the settlements.

As addressed previously, Dr. Williams cannot state that he currently believes the RE '516 patent to be infringed by the Generic Defendants' products, as the patent has been held to be invalid, and an invalid patent cannot be infringed. However, testimony regarding arguments made during the Paragraph IV litigation and the information available to the parties at that time regarding infringement would not offend Daubert's fit requirement. The mere fact that Cephalon did not advance a doctrine of equivalents argument at the time of the Paragraph IV litigation does not definitively establish that Cephalon never considered the doctrine of equivalents at the time of the reverse-payment settlements.

With respect to Plaintiffs' argument that Dr. Williams' doctrine of equivalents opinion is contrary to law, and thus, not reliable, I note that during the Apotex infringement trial, I did not determine whether Apotex's bioequivalent product would have infringed the RE '516 patent under the doctrine of equivalents. See Apotex, Inc., 2012 WL 1080148, at *6 (recognizing that

infringement may be demonstrated through literal infringement or doctrine of equivalents, and that Cephalon had argued literal infringement only). Further, Dr. Williams did not simply assume that bioequivalence automatically results in infringement under the doctrine of equivalents, but instead performed a detailed analysis under the function-way-result test, opining that:

> Ranbaxy and Teva's modafinil tablets perform substantially the same function (delivering modafinil to the human body), in substantially the same way (comparable dissolution and bioequivalent pharmacokinetic profiles), to achieve substantially the same result (improving wakefulness in patients having narcolepsy, obstructive sleep apnea/hypopnea syndrome, or shift work sleep disorder), as the pharmaceutical composition claimed in the '516 patent.

(Williams Exp. Rep., June 10, 2011, ¶ 32.) These principles ultimately led Dr. Williams to conclude that "a generic modafinil tablet could not have achieved bioequivalence to Provigil if the particle size distribution of the modafinil were outside the scope of claim 1." (See Williams Exp. Rep., June 10, 2011, ¶¶ 25-38, 43.) So while I agree with Plaintiffs that an expert cannot simply assume that bioequivalence results in infringement under the doctrine of equivalents, Dr. Williams' analysis goes beyond such an assumption. Therefore, I decline to exclude these opinions as unreliable.

D. The Motions to Preclude the "Reasonableness" Experts – Dr. Dahling, Mr. Gardner, and Mr. Ludwig

1. The Expert Report of Dr. Gerald Dahling

Dr. Gerald Dahling, a biologist and attorney, has been retained by Cephalon to provide expert opinions on the claims, defenses, and positions the parties asserted during the Paragraph IV litigation.[14] (Dahling Exp. Rep., June 10, 2011, ¶ 2.) Dahling's expert report reviews the RE

[14] Dr. Dahling also provides opinions on Cephalon's acquisition of licenses to modafinil intellectual property owned by the Generic Defendants. The admissibility of this testimony will be addressed in a later opinion.

'516 patent, the Hatch-Waxman regulatory framework, and the Paragraph IV certifications filed by the Generic Defendants. (Id. at ¶¶ 21-36.) It also explores, on an ex ante basis, the claim construction arguments made by Cephalon during the Paragraph IV litigation, the expert reports prepared by Cephalon's experts during that time period, and the arguments regarding validity, enforceability, and infringement that were asserted by the parties to the Paragraph IV litigation. (Id. at ¶¶ 37-177.) Upon reviewing all of this information, Dr. Dahling opines that Cephalon had strong claims in the Paragraph IV litigation, such that a reasonable litigant could realistically have expected success on the merits. (Id. at ¶¶ 3, 37-177.)[15]

2. The Expert Report of Mr. Paul Gardner

Mr. Gardner, an attorney, has been retained by Mylan to present opinions on the patent positions of the parties to the reverse-payment settlement agreements. (Gardner Exp. Rep., June 10, 2011, ¶ 1.) He reviewed the invalidity-related motions for summary judgment in the Paragraph IV litigation and offered opinions on whether Cephalon's arguments and supporting evidence were sufficiently well-founded and strong that, ex ante, a reasonable litigant could have expected the RE '516 patent to survive summary judgment. (Id. at ¶ 3.) Mr. Gardner also considered whether it would have been prudent for reasonable litigants to resolve the Paragraph IV litigation. (Id. at ¶ 4.) Ultimately, Mr. Gardner concludes that, based on the evidence and arguments put forth by Cephalon at the time of the settlements, a reasonable litigant could have expected the '516 patent to survive the Generic Defendants' summary judgment motions on invalidity. (Id. at ¶¶ 26, 30, 35, 50, 53, 58.) Mr. Gardner also opines that it was prudent for

[15] Dr. Dahling also opines that Cephalon's settlement of the Paragraph IV litigation was reasonable to resolve litigation uncertainty that Cephalon faced, including the risk of losing exclusivity in marketing its flagship product, which constituted a significant percentage of Cephalon's revenue stream. (Id. at ¶¶ 178-81.) For the reasons stated in my October 2015 Opinion, these opinions will be excluded for failure to fit the facts of the case. See King Drug Co. of Florence, Inc. v. Cephalon, Inc., 2015 WL 5783603, at *8 (E.D. Pa. Oct. 5, 2015).

Mylan to settle their patent dispute because Cephalon presented strong arguments in favor of patent validity, and had Mylan lost the litigation, it would have been held off of the market through the expiration of the RE '516 patent. (Id. at ¶¶ 59-62.)

3. The Expert Report of Mr. S. Peter Ludwig, Esq.

Mr. Ludwig, an attorney, has been retained by Ranbaxy to present opinions on how he would have advised Ranbaxy to proceed in the fall of 2005 regarding the litigation with Cephalon. (Ludwig Exp. Rep., June 10, 2011, ¶ 2.) Mr. Ludwig opines that, due to the uncertainties that Ranbaxy faced in the Paragraph IV litigation, and the chance that the RE '516 patent would be upheld as valid, he would have counseled Ranbaxy to attempt to settle the litigation and enter the market three years prior to the patent's expiration. (Id. at ¶¶ 23, 26.) Such a settlement would avoid the dangers inherent in an at-risk launch, particularly where Ranbaxy's potential gains from at-risk launch were limited by its shared first-filer status. (Id. at ¶¶ 24-25.) Mr. Ludwig also asserts that patent litigation is expensive, both in terms of money and time, which can factor into a decision to settle the litigation. (Id. at ¶ 27.) Ultimately, Mr. Ludwig concludes that, in light of all of these factors, Ranbaxy's decision to settle the Paragraph IV litigation with Cephalon was reasonable, and is the decision he would have counseled Ranbaxy to make at the time. (Id. at ¶¶ 79-86.)

4. Legal Analysis

i. *Plaintiffs' Reliability and Fit Challenges*

Plaintiffs challenge these experts for making statements that conflict with this Court's prior findings in the Apotex patent litigation. For the reasons previously discussed, these experts will not be permitted to opine that the patent is presently valid, or to adopt as true legal standards that directly conflict with the conclusions of law established by my validity ruling in the Apotex

patent litigation.[16] These experts are, however, permitted to explain the Hatch-Waxman legal framework and the arguments made during the Paragraph IV litigation.

As to Mr. Gardner and Mr. Ludwig, the Generic Defendants seem to argue that my prior rulings in the Apotex litigation do not have preclusive effect in their antitrust case, citing to my collateral estoppel opinion. Specifically, the Generic Defendants rely upon my statement that "the fact that the patent was found invalid in the 2011 Apotex patent litigation should have no bearing on the proofs necessary to hold the Generic Defendants liable for antitrust violations." King Drug Co. of Florence, Inc., 2014 WL 982848, at *13. The Generic Defendants misconstrue the effect of this statement. At no point did I rule that the Generic Defendants were permitted to argue that the patent was valid or that invalidity did not have a preclusive effect as to the Generic Defendants. Instead, I found that "[t]he Generic Defendants will still be able to argue, should they so choose, that settlement was pro-competitive, and that they were unaware of Cephalon's alleged fraud or the invalidity of the patent." Id. Accordingly, the Generic Defendants' experts may present expert testimony regarding patent positions to attempt to demonstrate that they were unaware of the patent's invalidity, but that is very different from opining that the patent is valid.

ii. *Apotex's "Legal Opinion" Argument*

Apotex separately challenges Dr. Dahling, Mr. Gardner and Mr. Ludwig[17] for presenting what it characterizes as impermissible legal opinions. The contested opinions state that various

[16] To the extent that Dr. Dahling, Mr. Gardner and Mr. Ludwig rely upon opinions presented by the validity and infringement experts, where I have found that those other experts' opinions are inadmissible for unreliability or lack of fit, these experts are also prohibited from restating those precluded opinions.

[17] In its motion, Apotex also challenges Cephalon's experts, Dr. Dahling and Ian Karet, for making improper legal conclusions in assessing the reasonableness of Cephalon's agreement to license various Generic Defendants' intellectual property. These aspects of the motion are taken under advisement and will be addressed separately.

legal arguments made by Cephalon during the Paragraph IV litigation were "reasonable" and that a reasonable litigant in Cephalon's position could have realistically expected success on the merits. Apotex urges that this testimony constitutes legal opinions presented by lawyers who are simply applying patent law to the underlying facts of the Paragraph IV litigation, such that their conclusions usurp the roles of the judge and jury. Apotex cites a number of cases where testimony regarding objective reasonableness has been excluded as a legal opinion that is not helpful to the jury. See Berckeley Inv. Grp., Ltd. v. Colkitt, 455 F.3d 195, 217 (3d Cir. 2006); QVC, Inc. v. MJC Am., Ltd., 2012 WL 13565, at *2 (E.D. Pa. Jan. 4, 2012); In re Wellbutrin SR Antitrust Litig., 2010 WL 8425189, at *3 (E.D. Pa. Mar. 31, 2010).

Cephalon responds that Dr. Dahling does not present a legal opinion, but instead opines as to the customs and practices of the industry and the factors considered by Defendants in deciding to settle the Paragraph IV litigation. See Berckeley, 455 F.3d at 218 (expert opinion on the customs and business practices in securities industry permissible as providing context that would aid the jury in determining the defendant's scienter). Cephalon further cites to In re Flonase Antitrust Litig., 884 F. Supp. 2d 184 (E.D. Pa. 2012), a case involving alleged sham citizen petitions, where the defendant offered an expert opinion that the petitions had "regulatory merit" and were "appropriate." Id. at 196-98. The court permitted the expert to testify that the petitions were within the FDA's jurisdiction, but did not permit the expert to use the term "appropriate," for fear of confusing the jury. Id. at 197. The court also allowed testimony that the petitions had "regulatory merit," finding that this opinion assisted the jury in deciding the objective prong of the analysis. Id. at 198. Relying upon Flonase, Cephalon asserts that Dr. Dahling's reasonableness opinions are admissible.

The Generic Defendants separately argue that Mr. Gardner and Mr. Ludwig do not provide impermissible legal conclusions and point to Federal Rule of Evidence 704, which provides that an expert opinion is "not objectionable just because it embraces an ultimate issue." They further argue that the precedent cited by Apotex is inapposite because the experts in those cases applied the governing law of the case to the facts in order to opine on the ultimate issue that the jury was tasked with deciding. The Generic Defendants explain that is not the case with respect to Mr. Gardner and Mr. Ludwig because the objective reasonableness (or unreasonableness) of the parties' patent positions is not an element of an Actavis claim. While Apotex has brought a sham litigation claim, which does require a plaintiff to prove that no reasonable litigant could have expected success on the merits, that claim has only been raised against Cephalon and not the Generic Defendants. Therefore, according to the Generic Defendants, Mr. Gardner and Mr. Ludwig's opinions do not usurp the role of the jury. Finally, the Generic Defendants argue that the experts, particularly Mr. Ludwig, provide valuable insights for the jury on the customs in the pharmaceutical industry and the factors considered by drug manufacturers when contemplating infringement settlements.

District courts "must ensure that an expert does not testify as to the governing law of the case." Berckeley, 455 F.3d at 217. Further, expert witnesses are prohibited from rendering a legal opinion because "it would usurp the District Court's pivotal role in explaining the law to the jury." Id. (citing First Nat'l State Bank v. Reliance Elec. Co., 668 F.2d 725, 731 (3d Cir. 1981)). "[An] expert [is] not free to reach conclusions about the reasonableness of [a party's] beliefs when such an opinion necessarily would have required an interpretation of the relevant . . . law." In re Wellbutrin SR, 2010 WL 8425189, at *3. "Expert testimony that 'merely tells the

[factfinder] what result to reach is improper.'" QVC, Inc., 2012 WL 13565, at *2 (quoting Burger v. Mays, 176 F.R.D. 153, 156 (E.D. Pa. 1997)).

The above-cited precedent must be viewed in the context of the claims at issue. Regarding its sham litigation claim against Cephalon, Apotex must demonstrate that: (1) the Paragraph IV litigation between Cephalon and the Generic Defendants was objectively baseless, such that "no reasonable litigant could realistically expect success on the merits"; and (2) the "baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor, through the use of the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon." Prof'l Real Estate Inv., Inc., 508 U.S. at 60-61 (quotation marks and citations omitted). Regarding its Actavis claims against all Defendants, Apotex must demonstrate that Cephalon made a large payment to the Generic Defendants that induced them to settle the patent litigation and which resulted in anticompetitive effects, and that, when considering any procompetitive justifications for the payment raised by Defendants, the reverse-payment settlements, on balance, impose an unreasonable restraint on competition. See King Drug Co. of Florence, Inc., 88 F. Supp. 3d at 415-16.

With respect to Apotex's sham litigation claim against Cephalon, I conclude that the reasonableness opinions of Dr. Dahling are not helpful to the jury. Whether Cephalon presented reasonable claims during the underlying litigation, such that it could have realistically expected success on the merits is an element Apotex must prove to the jury in order to establish sham litigation. The reasonableness opinions proposed by Dr. Dahling can only be derived by applying the legal standards of invalidity and infringement to the relevant facts and assessing their legal merit. Such opinions would clearly usurp the role of the jury and merely tell them which conclusion to reach as to an essential element.

The Honorable Lawrence F. Stengel of this court considered "reasonableness" opinions similar to those offered by Dr. Dahling in In re Wellbutrin SR Antitrust Litigation. There, the plaintiffs sought to introduce expert opinions in an antitrust case involving a sham litigation claim. The two attorney experts opined that the defendant could not have had a reasonable expectation of success in the litigation. Judge Stengel found that these opinions constituted legal opinions, as they were derived by applying the relevant facts to the governing legal standards during the relevant time period. In re Wellbutrin SR, 2010 WL 8425189, at *4-6. Judge Stengel granted the defendants' Daubert motion as to the experts' analysis of legal standards, as well as the conclusion that the defendant did not have a reasonable expectation of success on the merits, reasoning that an expert invades the role of the jury when it merely presents legal conclusions by applying facts to law. Id. at *6. I agree with Judge Stengel's analysis. While Cephalon relies upon In re Flonase to support admission of Dr. Dahling's reasonableness opinions, that case did not consider whether the expert's opinions should be excluded as a legal opinion, and therefore, does not assist Cephalon's argument.

I understand that Federal Rule of Evidence 704 provides that an opinion is not objectionable just because it embraces an ultimate issue in the case. But that Rule's application notes provide additional context, explaining that courts must still consider: (1) whether the opinion is helpful to the jury under Rule 702; (2) the potential prejudice under Rule 403; and (3) whether the opinion "merely tell[s] the jury what result to reach." Fed. R. Evid. 704 advisory committee's note. For example, "the question, 'Did T have capacity to make a will?' would be excluded, while the question, 'Did T have sufficient mental capacity to know the nature and extent of his property and the natural objects of his bounty and to formulate a rational scheme of distribution?' would be allowed." Id. While this is a simple illustration applied to a more

complex set of facts, the same evidentiary principle applies: an expert's opinion that draws on legal conclusions and merely tells the jury what conclusion to reach is normally not permitted. As such, I conclude that, as to Apotex's sham litigation claim, expert opinions that legal arguments made during the Paragraph IV litigation were reasonable or that Cephalon had a realistic expectation of success on the merits will be excluded.

The issue regarding the admissibility of "reasonableness" opinions becomes more nuanced when considering the Actavis claims. As I have explained previously, Defendants may present evidence offered to demonstrate the strength of their patent positions in the Paragraph IV litigation in defending against Plaintiffs' Actavis claims. That evidence may take the form of explaining the legal standards and information that was available to the settling parties on an ex ante basis, as well as explaining the arguments that were raised by the parties during the Paragraph IV litigation. But Defendants seek to take the testimony of Dr. Dahling and Mr. Gardner one step further, and include opinions that those arguments made during the Paragraph IV litigation were reasonable—i.e. that they had legal merit.

For many of the same reasons set forth in In re Wellbutrin SR, I conclude that, as to the Actavis claims, Dr. Dahling and Mr. Gardner's testimony that the legal arguments made during the Paragraph IV litigation were reasonable will not be helpful to the jury and will be excluded. The proposed experts are attorneys who are evaluating the merits of a legal argument by applying the facts to the law, which invades the jury's role. See United States v. Barile, 286 F.3d 749, 760 (4th Cir. 2002) ("Expert testimony that merely states a legal conclusion is less likely to assist the jury in its determination"); Hygh v. Jacobs, 961 F.2d 359, 363-64 (2d Cir. 1992) (excluding expert legal opinions regarding the reasonableness of the use of force in a civil rights case for merely telling the jury what conclusion to reach); FedEx Ground Package Sys., Inc. v.

Applications Intern. Corp., 695 F. Supp. 2d 216, 221-22 (W.D. Pa. 2010) (excluding expert testimony as an impermissible legal opinion where "opinions result from nothing more than an application of law to the facts in issue as alleged by [the defendant]").[18]

This conclusion is further supported by the fact that both Dr. Dahling and Mr. Gardner are attorneys presenting legal opinions. Allowing an attorney expert to testify about the legal merits of certain arguments made during litigation would "amount[ ] to nothing more than advocacy from the witness stand." Sundance, Inc. v. DeMonte Fabricating Ltd., 550 F.3d 1356, 1364-65 (Fed. Cir. 2008). Accordingly, Dr. Dahling and Mr. Gardner's opinions that legal arguments were reasonable, and their opinions as to whether it would have been reasonable to expect success on the merits, will be excluded as impermissible legal opinions. (See, e.g., Dahling Exp. Rep., June 10, 2011, ¶¶ 2(a), 3(a), 37, 46, 65, 79, 111-12, 118, 128, 134-35, 142, 157, 168, 177; Gardner Exp. Rep., June 10, 2011, ¶¶ 26, 30, 35, 50, 53, 57-60.)

Although Dr. Dahling and Mr. Gardner may not present their opinions that certain arguments made during the Paragraph IV litigation were reasonable or that Cephalon would have been reasonable to expect success on the merits, I do not find that their opinions should be excluded in their entirety. As previously described, Dr. Dahling provides background information on the RE '516 patent, the Hatch-Waxman regulatory framework, and the arguments raised by the parties during the Paragraph IV litigation with respect to claim construction, patent

[18] Additionally, in light of my conclusion that these reasonableness opinions are not helpful to the jury with respect to the sham litigation claim, to allow identical or nearly identical testimony to be presented, but only regarding Plaintiffs' Actavis claims, would be unmanageable and create a significant likelihood of confusing the jury. Therefore, an additional reason to exclude Dr. Dahling's and Mr. Gardner's reasonableness opinions is to avoid jury confusion and prejudice. See Fed. R. Evid. 403 ("The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury").

validity and infringement. Similarly, Mr. Gardner explains the arguments Cephalon, Mylan and Ranbaxy raised in the Paragraph IV litigation.

The jury will be tasked with determining whether Apotex has proven its sham litigation and Actavis claims. Both of these claims require an understanding of the arguments set forth during the Paragraph IV litigation and complicated aspects of patent law and administrative frameworks. Because the Hatch-Waxman framework, the procedural history of this case, and various aspects of patent law may be difficult for a layperson to understand, testimony providing this background will be helpful to the jury, and will therefore be permitted. See In re Wellbutrin SR, 2010 WL 8425189, at *3; Univ. Rehab Servs., Inc., 1996 WL 297575, at *10 ("expert testimony is viewed as helpful in cases, like this one, involving complex statutes or issues outside the general knowledge of the jury").

With respect to Mr. Ludwig, I find that his opinions are generally distinguishable from those presented by Dr. Dahling and Mr. Gardner. Mr. Ludwig comments upon the business risks faced by Ranbaxy in continuing the Paragraph IV litigation or in launching at risk. (Ludwig Exp. Rep., June 10, 2011, ¶¶ 23-28.) Based upon the potential liabilities, expenses, and damage to Ranbaxy's business that could result from an unsuccessful challenge to the RE '516 patent or an at-risk launch, Mr. Ludwig concludes that Ranbaxy's decision to settle was reasonable. (Id. at ¶¶ 79-86.) This testimony is more along the lines of evidence regarding relevant considerations and customs of a business engaging in patent litigation. See United States v. Leo, 941 F.2d 181, 196-97 (3d Cir. 1991) (expert opinion on business customs and practices permissible so long as expert does not give opinions about legal duties arising under the law). Mr. Ludwig, unlike Dr. Dahling or Mr. Gardner, does not opine upon the reasonableness of the legal arguments put forth during the Paragraph IV litigation, but instead focuses upon the unpredictability of litigation and

how resolution of that risk provides procompetitive benefits. I previously found that the Generic Defendants may present this type of testimony.[19] King Drug Co. of Florence, Inc., 2015 WL 5783603, at *9.

However, I reach a different conclusion with regard to Mr. Ludwig's final opinion that, "[u]nder the circumstances set forth above, [he] would have counseled Ranbaxy to attempt to settle the RE '516 Patent Litigation." (Ludwig Exp. Rep., June 10, 2011, ¶ 86.) I agree with Apotex that this opinion has a significant likelihood of prejudicing Apotex and confusing the jury. See Fed. R. Evid. 403 ("The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury"). Given the complex nature of the proceedings, the jury may mistakenly conclude that Ranbaxy actually relied upon Mr. Ludwig's advice in settling the Paragraph IV litigation. This would be a particularly prejudicial result where Ranbaxy has consistently refused to provide any

[19] I disagree with Apotex's argument that Mr. Ludwig is not qualified to opine on the business considerations that may be weighed in deciding whether to settle the patent litigation. Even if Mr. Ludwig's extensive experience as an attorney in patent prosecution, litigation and counseling numerous clients on these matters were insufficient, Ludwig supplements his own opinions with the testimony of Ranbaxy's Vice President and Regional Director for the Americas, Venkatachalam Krishnan. (Gardner Exp. Rep., June 10, 2011, ¶¶ 2, 5-22.) Although Apotex objects to Mr. Ludwig's use of Krishnan's testimony, arguing it is a "conduit for hearsay," Federal Rule of Evidence 703 permits an expert to base his opinion "on facts or data in the case that the expert has been made aware of . . . [and] [i]f experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion[.] . . . [T]hey need not be admissible for the opinion to be admitted." In any event, Ranbaxy has indicated that it intends to call Krishnan as a witness, which would negate hearsay concerns.

I further disagree with Apotex's position that the benefits of settlement can never be taken into consideration in an Actavis rule of reason analysis. While Apotex is correct that the merits of settlement cannot justify the payment, that does not mean that it is irrelevant to the broad balancing test under the rule of reason. Such evidence may give the jury additional context for determining why the parties chose to settle, which is one of the questions the jury must answer in performing its rule of reason analysis.

discovery on its motivations in settling the litigation and any advice received due to its assertion of the attorney-client privilege. Accordingly, this opinion will be excluded.

In conclusion, I find that the reasonableness opinions of Dr. Dahling and Mr. Gardner and the opinion set forth by Mr. Ludwig that he would have counseled Ranbaxy to settle the Paragraph IV litigation will be excluded as unhelpful to the jury under Rule 702, as well as Rule 403.

IV. CONCLUSION

Plaintiffs' various Daubert motions to exclude the opinions of Defendants' ten patent experts are granted in part and denied in part. Generally, for the reasons described above, I find that Actavis does not preclude consideration of the strength or weakness of the RE '516 patent. However, Defendants experts must tailor their opinions to fit the facts of this case, and more specifically, my prior findings that have been granted preclusive effect. Defendants' patent experts must also refrain from offering impermissible legal conclusions on the reasonableness of certain arguments made during the Paragraph IV litigation.

An appropriate Order follows.